

REMARKS

Claims 1, 3-8, 10-12, 15-18, 21 and 23-25 are pending in this application. Claims 2, 9, 13, 14, 19, 20, 22 and 26 have been canceled.

New Claims 27-31 have been added to further clarify and define the invention disclosed in the present application. These claims find support in the specification of the application as originally filed and, thus, no new matter has been added by the introduction of the claims. Applicant respectfully requests examination and allowance of Claims 27-31.

Applicant has amended Claim 18 solely for the purposes of clarifying the present invention and making the claim more easily readable, and not for the purpose of distinguishing prior art. No new matter has been added by this amendment.

The Examiner has rejected claims Claims 1, 3-8, 10-12, 15-18, 21 and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,938,969 to Schinitzky et al. (hereafter "Schinitzky"), in view of U.S. Patent No. 5,804,594 to Murad (hereafter "Murad"), in further view of U.S. Patent No. 5,902,591 to Herstein (hereafter "Herstein"), and in further view of U.S. Patent No. 2,517,276 to Bassford et al. (hereafter "Bassford").

The Examiner has also rejected claims Claims 1, 3-8, 10-12, 15-18, 21 and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Schinitzky, in view of Murad, in further view of U.S. Patent No. 5,140,043 to Darr et. al. (hereafter "Darr"), in further view of Bassford, and in further view of U.S. Patent No. 5,700,451 to Yue et al. (hereafter "Yue").

For at least the reasons set forth below, withdrawal of all outstanding rejections is respectfully requested.

Prior Art Rejections

Section 103(a) rejections:

The Examiner has rejected claims Claims 1, 3-8, 10-12, 15-18, 21 and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,938,969 to Schinitzky et al. (hereafter "Schinitzky"), in view of U.S. Patent No. 5,804,594 to Murad (hereafter "Murad"), in further view of U.S. Patent No. 5,902,591 to Herstein (hereafter "Herstein"), and in further view of U.S. Patent No. 2,517,276 to Bassford et al. (hereafter "Bassford").

The Examiner has also rejected claims Claims 1, 3-8, 10-12, 15-18, 21 and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Schinitzky, in view of Murad, in further view of U.S. Patent No. 5,140,043 to Darr et. al. (hereafter "Darr"), in further view of Bassford, and in further view of U.S. Patent No. 5,700,451 to Yue et al. (hereafter "Yue").

Applicant respectfully traverses all of the above rejections.

Applicant respectfully submits that the Examiner has suggested an improper (and highly improbable) hindsight combination of the cited references that – even if one of ordinary skill in the art could find motivation to make such highly speculative and selective modifications – would not successfully render all of the required elements of the pending claims.

Applicant notes that, in several instances, the Examiner provides – as motivation for such highly speculative and selective combinations of *six* disparate prior art references – “the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.”

Applicant respectfully notes, and respectfully reminds the Examiner, that such is *not* the proper standard for an obviousness rejection. In addition to finding every element of the invention in combined prior art references, one of *ordinary* skill in the art would – *prospectively* – have to find motivation or suggestion to combine the references in the manner suggested. In this case – in order to realize the prior art combinations suggested by the Examiner – one of ordinary skill in the art would prospectively have to find motivation or suggestion to combine highly selective elements from, and disregard significant portions of, *six* disparate prior art references.

In light of the following remarks, addressing each claim sequentially, Applicants respectfully request reconsideration and allowance of all claims pending in this application.

Claim 1:

Applicant respectfully traverses the Examiner's characterization of the disclosures and suggestions of the Schinitzky, Murad, Herstein, Bassford, Darr and Yue references.

Claim 1 of the present application requires a composition comprising at least about 5% (w/v) ascorbic acid, non-toxic zinc salt; and water; wherein the composition has a pH of 3.5 to 4.1.

Applicant finds that **Schinitzky contains no teaching or suggestion of pH values or their significance to the invention.**

Thus, in order to achieve the prior art combination of references allegedly rendering Claim 1 obvious, as suggested by the Examiner, one of ordinary skill in the art having only Schinitzky before him would have to: 1) read and fully understand Schinitzky; 2) spontaneously decide that the inventive composition in Schinitzky was somehow deficient or in need of

modification; 3) spontaneously assume, without prompting, that pH values of a composition should be of importance; and 4) seek out and find the Murad reference.

Applicant finds that Murad is directed to a pharmaceutical composition for the prevention of wrinkles and improvement of skin elasticity and softness. Murad discloses that **oral administration** of its composition **is preferred**, and presents its disclosure in reference to orally administered examples. (Col. 8, lines 43-46; Cols. 9-15).

Murad discloses a composition comprising a sugar compound (N-acetylglucosamine compound or salt or ester thereof, in ~ 5% – 50% w/v); a primary antioxidant component (an ascorbic acid component or salt or ester thereof , in ~ 5% – 50% w/v); an amino acid component (proline, lysine, cysteine, or methionine, in ~ 8% – 60% w/v); and a transition metal component (zinc, manganese or copper, or mixtures thereof, in ~ 0.5% – 15% w/v). Murad discloses embodiments that further comprise a catechin-based preparation; a glucosamine or a pharmaceutically acceptable salt or ester thereof; and a chondroitin or a pharmaceutically acceptable salt or ester thereof. Murad discloses still other embodiments that even further comprise a vitamin E source; a cysteine source; a vitamin B₃ source; a methionine source; a vitamin A source; and other various elements.

Applicant finds that Murad discloses the necessity of an amino acid (Col. 5; lines 14-18; Col. 6, lines 9-11), and includes such in all disclosed embodiments. Similarly, Murad discloses the necessity of a transition metal component (Col. 5; lines 22-24; Col. 6, lines 33-36), and includes such in all disclosed embodiments.

Murad discloses that **oral administration** of its composition **is preferred**. (Col. 8, lines 43-46; Cols. 9-15).

Applicant also finds that **Murad contains no teaching or suggestion of pH values or their significance to the invention.** Since Murad discloses oral administration as its preferred method, Applicant submits that the effect of pH value on dermal absorption is not even contemplated by Murad.

Thus, in order to achieve the prior art combination of references allegedly rendering Claim 1 obvious, as suggested by the Examiner, one of ordinary skill in the art would have to: 1) read and fully understand Schinitzky; 2) spontaneously decide that the inventive composition in Schinitzky was somehow deficient or in need of modification; 3) spontaneously assume, without prompting, that pH values of a composition should be of importance 4) seek out and find the Murad reference; 5) read and fully understand Murad; 6) disregard Murad's substantial teaching and suggestion of the preferability of *oral composition and administration*, selectively culling only a few elements from Murad's oral treatment to apply to Schinitzky's *topical* formulation; 7) spontaneously disregard Murad's teachings of the necessity of amino acids; 8) selectively disregard Murad's teaching of transition metals other than zinc sulfate; 9) again spontaneously assume, despite no teaching or suggestion by either Schinitzky or Murad, that pH values of a composition should be of importance; 11) successfully modify Schinitzky's topical composition to include elements of Murad's oral treatment; 12) again spontaneously assume that the resulting composition was still somehow incomplete or deficient; and 13) seek out and find the Herstein reference.

Applicant finds that Herstein is directed to a stable topical emulsion for cosmetic/pharmaceutical purposes, made from a two component system of a powdered ascorbic acid phase and a liquid phase. The liquid phase contains an effective amount of an organoclay

material to stabilize the emulsion. Applicant can find no disclosure with Herstein of a non-toxic zinc salt.

Thus, in order to achieve the prior art combination of references allegedly rendering Claim 1 obvious, as suggested by the Examiner, one of ordinary skill in the art would have to: 1) read and fully understand Schinitzky; 2) spontaneously decide that the inventive composition in Schinitzky was somehow deficient or in need of modification; 3) spontaneously assume, without prompting, that pH values of a composition should be of importance; 4) seek out and find the Murad reference; 5) read and fully understand Murad; 6) disregard Murad's substantial teaching and suggestion of the preferability of *oral composition and administration*, selectively culling only a few elements from Murad's oral treatment to apply to Schinitzky's *topical* formulation; 7) spontaneously disregard Murad's teachings of the necessity of amino acids; 8) selectively disregard Murad's teaching of transition metals other than zinc sulfate; 9) again spontaneously assume, despite no teaching or suggestion by either Schinitzky or Murad, that pH values of a composition should be of importance; 11) successfully modify Schinitzky's topical composition to include elements of Murad's oral treatment; 12) again spontaneously assume that the resulting composition was still somehow incomplete or deficient; 13) seek out and find the Herstein reference; 14) seek out and find the Herstein reference; 15) read and fully understand Herstein; 16) selectively cull from Herstein only the concept of the usefulness of a pH value of 3.5 to 4.1 – *despite no prior prompting from either Schinitzky or Murad*; and 17) successfully modify the Schinitzky/Murad combination to have a final pH value of 3.5 to 4.1.

Applicant notes that the teachings and suggestions of Bassford, Darr and Yue are addressed in later reference, where applicable to the other claims of the present application.

Applicant respectfully submits that, in light of the remarks made thus far, and the general similarity of the references, specific review of those references in relation to Claim 1 would be redundant and unnecessary.

Applicant does generally note, however, that the disclosure in Darr that transition metal ions catalyze oxidative degradation (Col. 2, line 4) would appear to teach away from combination with Murad, which discloses *the necessity of a transition metal component* (Col. 5; lines 22-24; Col. 6, lines 33-36).

Applicant respectfully submits that one of ordinary skill in the art, at the time the invention of the present application was made, would not be prompted or motivated by the cited references to embark on the highly speculative, selective, and unnavigable combination suggested by the Examiner, without the assistance of the present application's disclosure.

Absent such an improper hindsight reconstruction, the required elements of Claim 1 are not *prospectively* taught or suggested by the cited references. Moreover, the Examiner has already admitted that "the prior art does not expressly disclose the combination of at least 5% of ascorbic acid, non-toxic zinc salt, water and pH of 3.5 to 4.1."

Applicant respectfully submits that Claim 1 overcomes the obviousness rejections over the cited references. Claim 1 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 1.

Claim 2:

Claim 2 has been canceled.

Claim 3:

Claim 3 depends from allowable Claim 1 and provides further limitation distinguishing over the cited references. Applicant respectfully submits that Claim 3 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 3.

Claims 4-5:

Claims 4-5 depend from allowable Claim 1 and provide, at least, claim differentiation. Applicant respectfully submits that Claims 4-5 stand in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claims 4-5.

Claims 6-8:

Claims 6-8 depend from allowable Claim 1 and provide further limitations distinguishing over the cited references. Applicant respectfully submits that Claims 6-8 stand in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claims 6-8.

Claim 9:

Claim 9 has been canceled.

Claim 10:

Claim 10 depends from allowable Claim 1 and provides, at least, claim differentiation.
Applicant respectfully submits that Claim 10 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 10.

Claims 11-12:

Claims 11-12 depend from allowable Claim 1 and provide, at least, claim differentiation.
Applicant respectfully submits that Claims 11-12 stand in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claims 11-12.

Claims 13-14:

Claims 13-14 have been canceled.

Claims 15-17:

Claims 15-17 depend from allowable Claim 1 and provide, at least, claim differentiation.
Applicant respectfully submits that Claims 15-17 stand in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claims 15-17.

Claim 18:

Claim 18 has been amended, solely for the purposes of clarifying the present invention and making the claim more easily readable, and not for the purpose of distinguishing over any of the cited references. No new matter has been added by this amendment.

Applicant respectfully traverses the Examiner's characterization of the disclosures and suggestions of the Schinitzky, Murad, Herstein, Bassford, Darr and Yue references.

Claim 18 of the present application, as currently amended, requires a topical composition comprising an aqueous solution including at least about 5.0% (w/v) pre-treated ascorbic acid, a non-toxic zinc salt, and having a pH of 3.5 to 4.1.

Applicant notes that the Examiner has rejected Claim 18 on the same grounds as Claim 1. Applicant hereby incorporates the remarks made above in relation to Claim 1.

Applicant respectfully submits that Claim 18 overcomes the obviousness rejections over the cited references. Claim 18 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 18.

Claims 19-20:

Claims 19-20 have been canceled.

Claim 21:

Claim 21 depends from allowable Claim 18 and provides, at least, claim differentiation. Applicant respectfully submits that Claim 21 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 21.

Claim 22:

Claim 22 has been canceled.

Claims 23-24:

Claims 23-24 depend from allowable Claim 18 and provide further limitations distinguishing over the cited references. Applicant respectfully submits that Claims 23-24 stand in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claims 23-24.

Claim 25:

Claim 25 depends from allowable Claim 18 and provides, at least, claim differentiation. Applicant respectfully submits that Claim 25 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 25.

Claim 26

Claim 26 has been canceled.

New Claims:

Claims 27-31:

Claims 27-31 depend from allowable independent claims, and provide further limitations distinguishing over the cited references. Applicant respectfully submits that Claims 27-31 stand in allowable form.

Conclusion

Applicant respectfully submits that – in light of this response addressing the Examiner's rejections – the instant application, including Claims 1, 3-8, 10-12, 15-18, 21, 23-25, and 27-31, is in condition for allowance.

Applicants respectfully request reconsideration and withdrawal of the rejections, and allowance of all pending claims.

Respectfully submitted,



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